K071090 (pg. 1 of 2)

Zimmer TMT, Inc.
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510(k) Summary

JUN 29 2007

Submitter:	Zimmer Trabecular Metal Technology, Inc. 10 Pomeroy Road Parsippany, New Jersey 07054
Contact Person:	Kathleen Rutherford Associate Director, Regulatory Affairs Telephone: (973) 576-0139 Fax: (973) 884-8795
Date:	April 16, 2007
Trade Name:	The Trabecular Metal Glenoid- the Bigliani/Flatow Complete Shoulder Solution
Common Name:	Glenoid Component
Classification Name and Reference:	Prosthesis, shoulder, semi & non-constrained, metal/polymer cemented, 21 CFR 888.3660
Product Code:	KWS and KWT

DEVICE DESCRIPTION

The device is a monoblock glenoid component comprised of a Trabecular Metal base with an articular surface composed of direct compression molded polyethylene (UHMWPE). The TM Glenoid is designed to interface & articulate with Zimmer B/F humeral components and is available in one thickness option of 5 mm, and the same articular geometry and dimensions as the B/F Glenoid implants cleared in K022377 and K031449.

INDICATIONS FOR USE

Prosthetic replacement with this device may be indicated for the treatment of severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint; un-united humeral head fractures of long duration; irreducible 3- and 4-part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable. The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty. Humeral heads with heights greater than 27 mm may be used for difficult clinical management problems involving rotator cuff deficiency where arthrodesis or conventional non-

constrained arthroplasty is not acceptable. In the USA, the device must be cemented under the base (see surgical technique for details) or fully cemented in place.

SUBSTANTIAL EQUIVALENCE

Documentation was provided which demonstrated that the Gen III Trabecular Metal Glenoid B/F Complete Shoulder Solution is substantially equivalent to its predicate devices with respect to intended use/indications for use, materials, technological characteristics and basic principles of operation.

Device Technological Characteristics & Comparison to Predicate Device

The subject device possesses the same external articulating geometry and dimensions, the same minimum polyethylene thickness, and same sizing options as the predicate devices. The Trabecular Metal and direct compression molded UHMWPE materials, incorporated in the monoblock device are similar to numerous cleared Zimmer Trabecular Metal devices. This 510(k) covers changes in the geometry of the Trabecular Metal base, or keel, as well as a modification to the underside of the UHMWPE articular construct.

The modifications are designed to:

- increase the interfacial area for attachment between the Trabecular Metal and UHMWPE
- increase the interfacial area between the UHMWPE and the bone cement mantle
- decrease the likelihood of center pilot post damage during impaction/insertion
- increase the overall fatigue and static strength of the Trabecular Metal base, making it less susceptible to damage in instances where it is not completely supported

Conclusion

The Trabecular Metal Glenoid is substantially equivalent to the identified predicate TM Glenoid devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 9 2007

Zimmer Trabecular Metal Technology, Inc.
% Ms. Kathleen Rutherford
Associate Director, Regulatory Affairs
10 Pomeroy Road
Parsippany, New Jersey 07054

Re: K071090
Trade/Device Name: The Trabecular Metal Glenoid – the Bigliani/Flatow (B/F) Complete Shoulder Solution
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, KWT
Dated: April 16, 2007
Received: April 18, 2007

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071090

Device Name: The Trabecular Metal Glenoid- Bigliani/Flatow® The Complete Shoulder Solution

Indications for Use:

Prosthetic replacement with this device may be indicated for the treatment of severe pain or significant disability in degenerative, rheumatoid, or traumatic disease of the glenohumeral joint; un-united humeral head fractures of long duration; irreducible 3- and 4-part proximal humeral fractures; avascular necrosis of the humeral head; or other difficult clinical management problems where arthrodesis or resectional arthroplasty is not acceptable. The assembled humeral component may be used alone for hemiarthroplasty or combined with the glenoid component for total shoulder arthroplasty. Humeral heads with heights greater than 27 mm may be used for difficult clinical management problems involving rotator cuff deficiency where arthrodesis or conventional non-constrained arthroplasty is not acceptable. In the USA, the device must be cemented under the base (see surgical technique for details) or fully cemented in place.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative and Neurological Devices

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